K 123768

STERIS®

JUL 2 6 2013

510(k) Summary
For
Reliance™ Advance Endoscope Processing System

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Summary Date: July 26, 2013

K 123768

1. **Device Name**

Trade Name:	Reliance Advance Endoscope Processing System
Common/usual Name:	Automated Endoscope Reprocessor
Classification Name:	21 CFR 876.1500 Endoscope Cleaning Germicide Accessories
Device Class:	II
Product Code:	NZA

2. **Predicate Device**

Reliance Endoscope Processing System (EPS) - K102244

EVOTECH Endoscope Cleaner and Reprocessor (ECR) - K061899

3. **Description of Device**

The Reliance Advance Endoscope Processing System is an economical, easy-to-use cleaning and high level disinfection system that can clean and high level disinfect up to two immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes and related accessories.

The system utilizes Reliance™ DG Dry Germicide, a proprietary, safe, dry peracetic acid generating oxidative chemistry. The Reliance Advance Endoscope Processing System was designed to be versatile in meeting the growing demands of the modern flexible endoscope processing department, while offering the highest level of patient and staff safety. The Reliance Advance Endoscope Processing System is a combination of products that are used to clean and high level disinfect flexible endoscopes and their accessories.

- The **Reliance Advance Endoscope Processor** is an electromechanical washer/high level disinfector with a microprocessor-based controller that provides for automated endoscope processing cycles and processor self-decontamination cycles.
- The proprietary enzymatic detergent is dispensed automatically during the Cleaning phase of the cycle to effectively clean endoscope(s) and accessories.
- **Reliance DG Dry Germicide** is a proprietary, two-part, dry, single-use oxidative chemistry, designed to generate the high level disinfection solution upon automatic dilution in water within the Reliance Endoscope Processor.
- Various accessories are available to accommodate the processing needs of specific endoscopes and endoscopic accessories.
- VERIFY Process Indicator for Reliance EPS is available to monitor for the effective dose of the Reliance DG active ingredient, peracetic acid.

- CIP 200 Acid-Based Process and Research Cleaner, a general cleaning agent, is used in one of the two self-decontamination cycles provided by the processor.

The **Reliance Advance Endoscope Processing Cycle** can perform endoscope leak testing and integrity monitoring throughout the following standardized cycle:

⇒ The first part of this cycle is a standardized, non-optional **cleaning phase** that consists of a dynamic wash using proprietary enzymatic detergent, followed by a rinse. In this phase, a controlled quantity of the concentrated enzymatic detergent is dispensed into the circulating warm water volume in the processor, forming an effective cleaning solution that is directed through endoscope lumens and onto all device surfaces.

The Reliance cleaning phase can be used in place of manual cleaning by the user. It does not replace the bedside pre-cleaning performed in the procedure room.

⇒ The second part is a non-optional **high level disinfection phase**; its parameters cannot be changed by the user. In this phase, the proprietary Reliance DG components, provided in a single use container, are dissolved with water at ~50°C to create the peracetic acid disinfection solution that is circulated throughout the processor and through device lumens for a 6 minute exposure time.

⇒ Following high level disinfection, the Reliance Advance Endoscope Processor removes the germicide use-dilution through a **rinse phase** which is non-optional; the parameters cannot be changed by the user. The processor filters the rinse water (as well as all of the water used throughout the cycle) through a 0.2 micron bacterial-retentive filter. There is an automatic internal integrity check of this filter at the end of each processing cycle. If the integrity check fails, an alarm alerts the user, and the processor does not complete the cycle.

⇒ The last step in the processing cycle is an **air purge phase** using HEPA-filtered air. The air purge helps to remove excess rinse water from the processed devices. The final air purge is preset to run for 4 minutes; additional air purge time may be selected by the operator.

⇒ At the end of each cycle the processor prints a detailed **cycle summary** with information such as processor number, date, start and stop times, and phase parameters. With an optional bar code reader, the printouts can also include identification numbers for the operator, patient, device, doctor and procedure.

The processor features two decontamination cycles that are to be used without endoscopes in the processor:

⇒ D-SHORT consists of hot water circulating through the processor for 10 minutes, followed by a 10-minute hot air purge. This cycle is to be run every 54 hours. D-SHORT is intended to prevent biofilm from forming.

⇒ The second, called D-LONG, consists of a cycle in which CIP 200 Acid-Based Process and Research Cleaner is added to hot water and circulated through the processor for 20 minutes; this is followed by three rinses to

remove the solution, and a 10-minute hot air purge. D-LONG is used when the D-SHORT cycle has not been run within the past 54 hours.

4. Intended Use

The Reliance Advance Endoscope Processing System is intended for cleaning and high level disinfection of up to two immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes and their accessories.

During the system's Endoscope Processing Cycle, cleaning is achieved within the Cleaning Phase, and high level disinfection is achieved within the 50 – 57°C HLD Phase (4 minute generation sequence followed by a 6 minute exposure sequence).

Manual cleaning is not required prior to processing in Reliance Advance Endoscope Processing System.

5. Technological Characteristics

The Reliance Advance Endoscope Processing System is not significantly different from the predicate Reliance EPS in technology. Technological modifications of the Reliance EPS design for the Reliance Advance Endoscope Processing System are summarized below:

Property ▼	Proposed Reliance Advance Endoscope Processor	K102244 STERIS Reliance Endoscope Processor
Endoscope Processing Cycle	The standardized Endoscope Processing Cycle (with one or two endoscopes) includes a Cleaning phase and its rinse, which is followed by the HLD phase, final rinses, and air purge.	In the Endoscope Processing Cycle (with one or two endoscopes) the user has the option to select zero, one or two Wash phases of 5 – 10 minutes each including a rinse, which is followed by the HLD phase, final rinses, and air purge.
Enzymatic Detergent and Dose Control	Peristaltic pump injects a metered volume of the proprietary new enzymatic detergent during the Cleaning phase. A flow meter provides feedback to the microprocessor to verify that the required volume of enzymatic detergent was injected by the peristaltic pump.	Peristaltic pump injects a metered volume of Klenzyme during Wash phases.

The Reliance Advance Endoscope Processing System is technologically similar to the EvoTech Endoscope Cleaner and Reprocessor (ECR) predicate, as shown in the comparison table below.

Property ▼	Proposed Reliance Advance Endoscope Processor	K061899 EvoTech Endoscope Processor
Control	Microprocessor-controlled programmable processor monitors and controls critical cycle parameters and provides a printed record upon cycle completion.	Microprocessor-controlled programmable processor monitors and controls critical cycle parameters and provides a printed record upon cycle completion.
Capacity	One or two endoscopes and accessories	One or two endoscopes and accessories
Mechanism for channel access	Uses a pressurized control handle boot such that operation is largely connector-less. Flow Units are used for specialized device processing needs.	Relies upon multiple tubings and connectors to provide flow to inner channels of endoscopes.
Enzymatic Detergent	Requires use of a proprietary enzymatic detergent for cleaning.	Requires use of a proprietary enzymatic detergent for cleaning.
Germicide	Requires Reliance DG Dry Germicide.	Requires Cidex OPA.
Monitoring	Requires use of a VERIFY Process Indicator for Reliance EPS strip with each Endoscope Processing Cycle.	Has an on-board concentration monitor.
Rinsing	Devices are rinsed with filtered water.	Devices are rinsed with filtered water.
Leak Test	Automated leak test is selectable.	Automated test assures absence of major leaks in the endoscope body.
Alcohol flush	Not provided	Selectable in this system
Self-Disinfection	Has capacity to perform self-disinfection.	Has capacity to perform self-disinfection.

6. Description of Safety and Substantial Equivalence

The Reliance Advance Endoscope Processing System has the same intended use for cleaning and high level disinfection of flexible endoscopes as the predicate EvoTech ECR. It is substantially equivalent to the EvoTech ECR with respect to achieving cleaning and high level disinfection of a wide range of flexible endoscopes and accessories.

7. Performance Testing Summary

Reliance Advance Endoscope Processing System Performance Testing Summary	
Cleaning Phase Efficacy	• Cleaning Phase Effectiveness in Simulated Use Studies Reliance Advance EPS has been tested and shown to achieve effective cleaning of soiled flexible endoscopes and their accessories. Testing was performed on a diverse array of OEM endoscopes incorporating the most challenging design features for cleaning, and under worst case simulated use conditions with respect to soil levels, drying, enzymatic detergent concentration, water condition, and cleaning phase exposure time. Fifteen (15) heat-sensitive flexible endoscopes, dilators, and their accessories were soiled with select test soils at levels appropriate to the intended use of the instrument. After the worst case Reliance Advance EPS cleaning phase in simulated use, 1) all test articles were visually clean, and 2) all samples recovered from previously soiled areas for all test articles met the established acceptance levels defined as "clean" for protein, carbohydrates, and total organic carbon in validated assays for those components. • Cleaning Phase Effectiveness in Clinical In-Use Studies Efficacy of the Reliance Advance EPS Cleaning Phase was evaluated in use in a US hospital. Four types of flexible endoscopes (bronchoscopes, gastroscopes, colonoscopies, and duodenoscopes) and their accessories as listed in Reliance Advance EPS labeling were used in clinical procedures, pre-cleaned at the bedside, allowed to dry for 47 – 100 minutes, and then processed through the Reliance Advance Endoscope Processing Cycle's Cleaning phase only, according to the instructions for use. Cleaning endpoints were evaluated. In triplicate evaluations, each of the tested clinically soiled endoscopes 1) was visually clean, and 2) met the soil pre-determined "clean" acceptance levels for protein, carbohydrates, and total organic carbon in validated assays.
Enzymatic Detergent Stability	• Enzymatic Detergent Stability: The proprietary enzymatic detergent has been shown to be stable in its Bag-in-Box packaging through 12 months under representative storage conditions. This protocol of testing continues; the shelf life may be extended based on additional data meeting established acceptance criteria.
Software Validation	The Reliance Advance EPS software was developed and validated in accordance with the FDA requirements for a Major Level of Concern determination based on the recommendation in the *FDA Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities* dated August 1993. All acceptance criteria were met.

<table>
<tr><th colspan="3">Reliance Advance Endoscope Processing System Performance Testing Summary</th></tr>
<tr><td>Material Compatibility</td><td colspan="2">• Enzymatic Detergent Material Compatibility
The proprietary enzymatic detergent was evaluated for its effect on common materials of endoscope and accessory construction. After 300 processing cycles, no deleterious effects were observed other than minor cosmetic changes. No functional changes in flexible endoscopes were observed.
• Reliance DG Material Compatibility:
The system was previously evaluated for its effect on intact medical devices, including flexible endoscopes and/or common materials of device construction. After 300 processing cycles, no deleterious effects were observed other than minor cosmetic changes. No functional changes in flexible endoscopes were observed.</td></tr>
<tr><td>Processor Performance</td><td colspan="2">The critical process parameters for the processor (water temperature and volume, fresh DG container detection, boot pressure, water filter integrity testing, and delivery of cleaning and high level disinfection solutions) have each been evaluated in replicate under worst case conditions, and found to be within required specifications.
Each processor phase or cycle has been separately evaluated and shown to be effective under worst case conditions:
⇒ The standard Cleaning phase using STERIS's proprietary enzymatic detergent had no effect on generation of the active from Reliance DG in Reliance Advance EPS during the HLD phase of the Endoscope Processing Cycle.
⇒ The HLD and Rinse phases of the Endoscope Processing Cycle have been shown to be effective. The air purge phase effectively removes rinse water from processed devices. The filter integrity test system has been shown to reliably detect filter failure.
⇒ The two self-decontamination cycles were shown to be effective as follows in prior studies:
• D-LONG cycle – can disinfect the Reliance Endoscope Processor after a high level challenge with Pseudomonas aeruginosa followed by a 5 day inactive period;
• D-SHORT cycle – can kill bacteria that have potential to form biofilm.</td></tr>
<tr><td rowspan="4">Certification to electrical safety standards</td><td>ANSI/UL -61010-1, 2nd Ed.</td><td>Electrical equipment for measurement, control and laboratory use Part 1, 2nd Edition</td></tr>
<tr><td>CAN/CSA C22.2 61010-1, 2nd Ed.</td><td>Electrical equipment for measurement, control and laboratory use Part 1, 2nd Edition</td></tr>
<tr><td>IEC 61010-1:2001</td><td>Safety requirements for electrical equipment for measurement, control and laboratory use, Part 1: General requirements</td></tr>
<tr><td>IEC 61010-2-40, 1st Ed.</td><td>Safety requirements for electrical equipment for measurement, control and laboratory use –Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials</td></tr>
<tr><td>IEC 61326-1:2005, 1st Ed.</td><td>Electrical equipment for measurement, control and laboratory use, EMC requirements Part 1: General requirements</td></tr>
</table>

Reliance Advance Endoscope Processing System Performance Testing Summary	
Reliance DG Dry Germicide Efficacy	• Reliance DG Dry Germicide Use Solution Microbial Efficacy: Potency: Reliance DG has been tested and shown to generate an effective high level disinfection solution using the standard array of microbiological tests for germicidal efficacy. Prior to the current submission, the following testing was performed at conditions of use that were worst case with respect to germicide concentration, contact time, circulation, water hardness, temperature and artificial soiling. ⇒ Sporicidal: Reliance DG was proven to be sporicidal as defined by AOAC Sporicidal Activity Test with exposure time of 6 minutes. Confirmatory testing was completed successfully and supplemental confirmatory testing was completed in the Reliance Endoscope Processor. Potency was subsequently confirmed in the processor and in vitro using Reliance DG containers that were aged beyond the end of its shelf life. ⇒ Tuberculocidal: Reliance DG was proven to be tuberculocidal as defined by the AOAC Tuberculocidal Activity Test with an exposure time of 6 minutes. Potency was subsequently confirmed using Reliance DG aged beyond the end of its shelf life. ⇒ Virucidal: The Reliance Process was proven to reduce the viable population of poliovirus Type 1, adenovirus Type 5, and herpes simplex virus Type 1 by > 4 log10. ⇒ Bactericidal: Reliance DG was proven to be bactericidal as defined by the AOAC Bactericidal Activity Test with an exposure time of 6 minutes at worst case conditions, whether performed in situ or in vitro. ⇒ Fungicidal: Reliance DG was proven to be tuberculocidal as defined by the AOAC Tuberculocidal Activity Test with an exposure time of 6 minutes, whether performed in situ or in vitro. Simulated-Use: Reliance DG, at its minimum recommended concentration, reproducibly achieved greater than a 6 $\log^{10}$ reduction of *Mycobacterium terrae* in triplicate trials within the Reliance Endoscope Processor for each selected clinically relevant flexible endoscope and its accessory. The test articles represented the range of most challenging devices, accessories, and processing situations. In-Use: Three flexible endoscopes representing the range of types indicated in the product labeling were used in clinical procedures and processed according to instructions for use. In triplicate evaluations of each endoscope, no organisms were recovered after processing. Bioburden levels on the clinically used endoscopes after manual cleaning and before high level disinfection were determined to be as high as 10^5 CFU/device.
Reliance DG Stability	• Reliance DG Stability: Reliance DG has been shown to be stable for 18 months in the unopened moisture-resistant package at the stated conditions for storage. Once opened, the five Reliance DG containers within each package are to be used within two (2) weeks, or by the expiration date on the container, whichever comes first.

Reliance Advance Endoscope Processing System Performance Testing Summary	
Bio-compatibility	• Biocompatibility: The Reliance chemical formulations, as supplied in packaging as well as in use dilutions, can be safely handled and used by customers. Residues that may remain on medical endoscopes and accessories are below established residue limits and do not pose a risk to patients. Safety statements in product labeling are appropriate to the potential risk. ⇒ Enzymatic detergent components, reaction products, and residuals remaining on medical devices were evaluated for biocompatibility and possible risks to users including literature reviews of raw material toxicity data. Testing included *in vitro* cytotoxicity evaluations on extracts of processed devices and rinse water, and analysis for chemical residuals. ⇒ Reliance DG, its components, reaction products, and residuals remaining on medical devices have previously been evaluated for biocompatibility and possible risks to users. Testing included acute oral and ocular toxicity tests, dermal irritation studies, in vitro bacterial mutation genotoxicity studies, sensitization tests, and in vitro cytotoxicity evaluations; literature reviews of raw material toxicity data were also performed. Certain components in the single-use DG container, which under normal use conditions never contact the user, have the potential for irritation or skin sensitization; therefore appropriate warnings and instructions are displayed on labeling for the unusual event of a spill or container breakage. ⇒ Use dilution reaches non-cytotoxic levels with minimal dilution. ⇒ Biocompatibility testing of extracts from processed medical devices demonstrated that no toxic residuals remain on devices under worst case circumstances. The test data indicate that the worst case residue levels for the components of maximum potential risk are far below the allowable limits, and the processor final rinse water was found to be non-cytotoxic.
Performance of VERIFY CI for Reliance EPS	• Colorless (complete change) at end of Reliance Advance Endoscope Processing Cycle using the minimum recommended PAA dose of ≥11,500 mg/L PAA min • NOT colorless (incomplete change) at end of Reliance Advance Endoscope Processing Cycle using the minimum effective PAA dose of 9000 mg/L PAA min, or in a processing cycle without PAA

Conclusion:

The completed nonclinical performance testing has demonstrated that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

STERIS Corporation
Ms. Marcia L. Benedict
Senior Director, Regulatory Affairs
5960 Heisley Road
Mentor OH 44060

Re: K123768
Trade/Device Name: Reliance™ Advance Endoscope Reprocessing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NZA
Dated: June 27, 2013
Received: June 28, 2013

Dear Ms. Benedict:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123768

Device Name: Reliance™ Advance Endoscope Processing System

Indications For Use:

The Reliance™ Advance Endoscope Processing System is intended for cleaning and high level disinfection of up to two immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes and their accessories.

During the system's standardized Endoscope Processing Cycle, cleaning is achieved within the Cleaning phase, and high level disinfection is achieved within the 50 – 57°C HLD phase (4 minute generation sequence followed by a 6-minute exposure sequence).

Manual cleaning is not required prior to processing in Reliance Advance Endoscope Processing System.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S
2013.07.25 14:42:31 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123768